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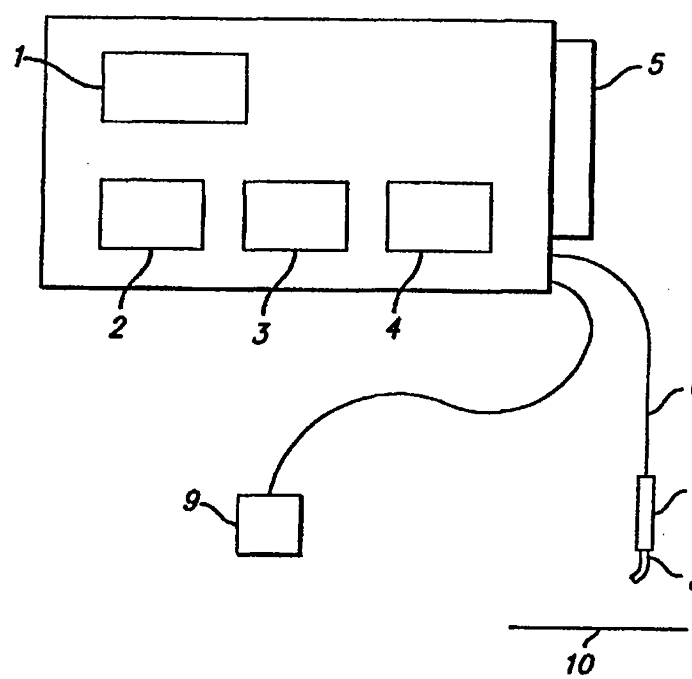
(54) Title: APPARATUS AND METHOD OF PHOTO-SPECIFIC TISSUE TREATMENT

(57) Abstract

An apparatus and related method are disclosed for directing a continuous or pulsed, polychromatic light beam through a hand-held light guide at a target biological tissue, as part of a health-related treatment in medicine or dentistry. The non-laser polychromatic light beam can be pulsed at a duration and duty cycle selected to provide optimal heating of the target issue, e.g., to temperatures in the range of 37° to 175 °C, while allowing the tissue to undergo a thermal relaxation response between successive pulses. The treatment delivers a photo-specific energy density in the range of 10 to 5000 watts/cm2, selected to achieve the desired treatment. In the case of dental procedures on hard dental tissue, such treatments can include tooth bleaching, curing of dental composite materials, detecting of caries, cutting of enamel, dentin and bone, desensitizing of dentin, etching of enamel, osteoplasty, ostectomy, shade matching and other cosmetic procedures, trans-illumination, imaging and/or illumination.



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APPARATUS AND METHOD OF PHOTO-SPECIFIC TISSUE TREATMENT

BACKGROUND OF THE INVENTION

The present invention relates generally to the use of non-coherent light in various health-related fields such as medicine, dentistry, and veterinary medicine. More specifically, the invention relates to the use of pulsed light to treat biological tissue.

Laser surgery is commonplace in modern dental practice. Reasons for laser use include minimization of both trauma during surgery and post-operative pain to the patient. Laser light has been used to stop bleeding, to cut tissue, to weld, and to coagulate tissue. This light/tissue interaction can cause non-specific photo-thermal changes that can result in reflection, absorption, scattering, and transmission of the light by the tissue. Details can be found in a reference entitled *Lasers in Dentistry*, by L.J. Miserendino and R.M. Pick, Quintessence Books, 1995.

Lasers can function to concentrate high densities of light energy on a very small spot. Very little of this light is diverged because of the coherent and collimated nature of laser light.

Many patents have issued in the field of using laser light as a tool in medical applications. Among these include ophthalmic treatments for macular degeneration, retinal attachment, and cataract removal. Patents also have issued relating to the use of laser light for hair removal, dermatology treatments, scar removal, and facial rejuvenation.

As one example, U.S. Patent No. 5,435,724 to Goodman et al. describes dental procedures and apparatus using pulsed ultraviolet light.

Specifically, ultraviolet light pulses are used to selectively etch both hard and soft tissue in dental procedures. Distinct ablation, or vaporization, thresholds exist for each type of tissue. This allows the dentist to perform both hard and soft tissue procedures without damaging healthy enamel, dentin, or the like.

Laser light has been widely applied in dentistry for soft tissue treatment and surgery. Laser light customarily is delivered via optical fibers, hollow waveguides, or articulated arms. Dental soft tissue treatment may include hemostasis, coagulation, ablation, and vaporization of soft oral tissue. Lasers have been used for periodontal treatment, gingiva surgery, frenum surgery, and the like. In fact, laser treatment of maxillary midline frenectomy is becoming a standard of care. Post-operative pain is rare when lasers are used for this procedure.

Medical, dental and veterinary procedures that use laser light function by raising tissue temperature. The table below indicates the effects on tissue as a function of temperature and energy.

TABLE 1

Tissue Effect (Watts/cm^2)	Temp (degrees C)	Energy
Hyperthermia	37-50	<10
Coagulation	50-60	100-500
Welding	70-80	500
Vaporization	90-100	500-1,000
Carbonization	100-150	1,000-5,000
Rapid Cutting	>175	>5,000

One advantage of laser soft tissue treatment is that the heat generated kills bacteria. It also provides a bloodless operating field, which results in less post-operative inflammation and pain.

Most laser procedures are contact, or near contact, surgeries, making the collimation feature not critical. In addition, laser light loses its coherent upon passage through a fiber optic. Since most dental lasers are delivered through fiber optics, the coherent characteristic is not necessary either. The important and necessary feature of the delivered light for medical, dental and veterinary procedures is its energy density.

In the past, conventional photo-thermal treatment of oral soft tissue has been accomplished using only certain approved lasers. These include visible light lasers such as argon and infrared lasers such as aluminum gallium arsenide diode, Nd:YAG, Ho:YAG, Er:YAG, and CO_2. These devices are very efficient in providing the desired photo-thermal effects on soft tissue.

According to dental and medical authorities, the advantages of using lasers, particularly CO_2 lasers, in oral surgery, include excellent hemostasis, improved viability during the procedure, minimal damage to adjacent tissue, reduced postoperative swelling, pain and infection, and a relative absence of scarring and wound contracture. These benefits have been attributed to the ability of the CO_2 laser to seal small blood vessels and lymphatics, which circumvent some of the inflammatory processes of wound healing. The CO_2 laser was limited in its early use by its inability to be effective in hard tissue, namely bone, enamel, cementum, and dentin.

Further work to broaden the application of lasers led to the Nd:YAG lasers in the 1980's. Research continues to develop new uses for dental lasers, for hard tissue procedures as well as various restorative procedures. Some of the procedures may be caries detection and prevention, cutting enamel, dentin, and bone, desensitization of dentin, enamel etching, osteoplasty, and ostectomy.

One drawback of these laser tools is that they are quite expensive to purchase and maintain. Also, certain lasers equipped with articulating arms are often cumbersome. Specifically, CO_2 lasers with articulated arms are often difficult to use for dental procedures. Additionally, the CO_2 laser beam is invisible. A visible He:Ne laser beam can be built coaxially, for use as an aiming device. Aiming an invisible light at soft tissue from a distance is difficult and risks adjacent tissue of being inadvertently hit by the laser beam.

The fact that lasers are monochromatic is an inherent limitation, because tissue absorption profiles are polychromatic. Because of this discrepancy, lasers offer a less than optimum and limited range of applicability in many dental and medical procedures.

Many medical, dental, and veterinary laser procedures are contact, or near contact surgeries, making the collimation feature of laser light not critical. In addition, laser light loses its coherent upon passage through a fiber optic. Since most dental lasers are delivered through fiber optics, the coherent characteristic is not necessary either. The important and necessary feature of the delivered light for medical and dental procedures is its absorption by tissue. This absorption raises the tissue temperature and causes the tissue effect.

Since the absorption profile for all tissues is a broad band of wavelengths, the monochromatic feature of laser light is also not necessary. In fact, more efficient transfer of energy occurs over the entire bandwidth of the absorption profile of the tissue.

It should therefore be appreciated that there is a need for an improved apparatus and related method for treating biological tissue as effectively as some of the laser systems described above, but without the associated drawbacks. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is embodied in an improved apparatus and related method for performing medical and/or dental procedures on a target biological tissue, with greater efficiency and without undue expense. The apparatus includes a light source for emitting a high-intensity light beam having an initial polychromatic spectrum, and a light guide having an inlet disposed at an effective focal position of the light source and a handheld outlet end, of small cross-section, configured to be disposed in proximity to the biological tissue to be treated. A pulsing device also can be included, for pulsing the light beam emitted by the light guide for a selected duration and duty cycle, such that the biological tissue being treated undergoes a thermal relaxation response between successive pulses. In addition, an optical filter can be included for tailoring the spectrum of the light beam directed to the target tissue for efficient interaction with the tissue.

In more detailed features of the invention, the apparatus further includes an adapter selectively attachable to the outlet end of the light guide, for directing a portion of the light beam emitted by the light guide to the biological

tissue to be treated. This adapter can be configured to carry the optical filter. Further, the pulsing device can be configured to allow an operator to independently control both the duration and the duty cycle of the successive pulses of light emitted by the apparatus. This pulsing device preferably is disposed between the light source and the light guide. The light guide preferably takes the form of an optical fiber assembly including a bundle of tightly packed optical fibers, with the inlet end of the optical fiber assembly having a diameter in the range of 1 to 2 mm.

In other more detailed features of the invention, the apparatus is configured to be suitable for use in dental procedures on hard dental tissue, including tooth bleaching, curing of dental composite materials, detecting of caries, cutting of enamel, dentin and bone, desensitizing of dentin, etching of enamel, osteoplasty, ostectomy, shade matching and other cosmetic procedures, trans-illumination, imaging and/or illumination. In such applications, the light source preferably is selected from the group consisting of halogen lamps, metal halide lamps, and plasma arc lamps, and it is configured to produce a light beam having a power level in the range of 12 to 500 watts. The polychromatic light beam directed to the biological tissue to be treated preferably has a power level of at least about 0.1 watt and includes wavelengths in the range of about 400 to 750 nm, and it has a photo-specific energy density in the range of 10 to 5000 watts/cm^2.

Other features and advantages of the present invention should become apparent from the following description of the preferred embodiment, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a simplified schematic drawing of a preferred embodiment of a photosurgery apparatus in accordance with the invention.

FIG. 2 is a more detailed diagram of the control panel portion of the photosurgery apparatus of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of this description, the terms 'medical,' 'dental' and 'veterinary' are used interchangeably. Most of the examples will be for dental applications of the light apparatus, but it is to be understood that the soft tissue treatments could be performed on any biological tissue.

The apparatus of the invention utilizes a special non-laser light source that is capable of delivering high power densities of a narrow wavelength distribution. The apparatus can perform contact or near contact treatment of tissue. The apparatus uses non-coherent visible light transmitted through a light guide, e.g., an optical fiber assembly, a hollow or liquid-filled waveguide, or an articulated arm, to deliver sufficient light energy to the tissue to controllably increase the tissue temperature. As can be seen in the above table, the increased tissue temperature results in hyperthermia, coagulation, welding, vaporization, carbonization, or rapid cutting.

The light source preferably is configured to emit visible light having a plurality of wavelengths and combinations of wavelengths in the visible and near infrared regions. A preferred wavelength spectrum is in the range of

400-750 nm, and preferably centered at about 565 nm. A 100-500 micron filter delivering at least 0.1 watt of continuous or selectively pulsed light to the tissue.

The apparatus of the invention overcomes the drawbacks associated with lasers by providing an inexpensive and versatile alternative to achieve comparable photo-thermal treatment. In the present invention, metal halide lamps are used which exhibit larger arcs of light energy. To couple a significant amount of light energy into a single transmission fiber requires that the fiber be larger than 600 microns. A single fiber would be too stiff and/or fragile to be used in the desired applications of this invention. In this invention, other means are used to transmit large amounts of light energy to tissue.

The arc sizes of the metal halide lamps used in this invention are made by Welch Allyn, Inc., of Skaneateles Falls, New York, and can be easily coupled into fiber bundles between 1 mm and 2 mm in diameter. With lamp powers of between 12 watts and 500 watts, such lamps achieve efficiencies which can provide between 2 to 5 watts of power coupled into and transmitted through a fiber optic bundle. The wattage not transmitted through the fiber optic bundle is dissipated as heat.

Coupling large amounts of non-coherent energy through small single strand fiber optic cable is known. To maintain flexibility, such single fibers must be no larger than 600 microns, typically 400 microns. To accomplish this, the energy source must be a short-arc arc lamp, at power levels ranging from 12 to 500 Watts, with special large diameter focusing optics to couple the required amount of energy into the fiber. The resulting high-intensity beam can be directed by the fiber tip directly into or onto tissue to achieve rapid photo-coagulation.

In this invention, a fiber optic bundle, consisting of many individual small diameter fibers configured in a tightly packed optimal configuration at the ends, is used to transmit light energy. This results in a fiber optic bundle with diameters larger than 600 microns and extremely flexibility. The end fibers are fused into solid entrance apertures of up to several inches in diameter, maintaining flexibility through the bulk of the length of the transmission cable and a relatively high transmission efficiency. Such a fiber bundle exhibits similar light transmission efficiencies as single fibers, with the exception of packing fraction losses. These losses are due to the cladding loss at the fiber entrance and they can usually be limited to not more than 30 to 35 % of the total amount of light transmitted. The increased diameter of the entrance aperture and resulting increased coupling efficiency can more than make up for this loss.

The tip of the fiber optic assembly can be a bare fiber, a sculpted tip, a tapered fiber optic bundle, a focusing handpiece, or a defocusing handpiece, depending on the spot size appropriate for the procedure to be performed. A defocused tip allows the light to spread out to a larger spot size. Focused light is used when contact surgery is being performed. Defocused light is used for illumination and for non-surgical procedures such as dental bleaching, shade matching, and curing composite dental resins. The tip of the fiber optic assembly also can connect to a cannula, for convenient use in directing the light to selected portions of the target tissue.

In this invention, the larger exit diameters for the fiber conduits (up to 600 microns), handpieces which condense the transmitted light energy into higher intensity spots are required. These handpieces may be disposable or removable to facilitate sterilization, and would consist of a lens or mirror which redirects the exiting light beam into a tightly focused spot. The lenses are either

discrete lenses spaced at an appropriate distance from the fiber exit to reduce the image size, or the end of the fiber optic cable can be figured into a focusing lens to produce the intense spot of light. Another possible approach for light delivery is to use a Selfoc™, or gradient index lens, attached at the end of the fiber optic bundle to produce the high-intensity spot at a distance from the end of the fiber. These approaches produce a high-intensity spot capable of performing dental, medical, and veterinary procedures on biological tissue with light at a distance of several millimeters to several inches from the fused fiber end of a lamp.

Yet another embodiment for delivering the light energy to the tissue includes a handpiece attached to a fiberoptic bundle, wherein the handpiece delivers the light through a focusing lens into a small cannula or hollow waveguide or sculptured sapphire tip, all of which could be used in or out of contact with the target tissue. The tips or cannulas could be detachable, autoclaveble or disposable. This embodiment could be used in contact with the tissue, or even in a procedure below the gingival tissue in the sulcus to treat periodontal disease and the like.

As can be seen from Figure 1, the apparatus of this invention is enclosed in a housing, which is preferably made of a combination of metal and injection molded plastic. The power supply 1 is internal, and may be either 110 or 220 volts. The light source 2, may be visible light such as halogen, metal halide, plasma arc or the like with an output of 12 to 500 watts. Multiple light sources are also considered to be within the scope of the present invention.

A pulse device 3 is configured to grate or optically chop the light beam emitted by the light source 2, to cause a strobe of the emitted light. The pulse device controls both pulse duration and duty cycle. Pulsing allows the treatment of tissue without anesthetic, which benefits both the doctor and the

patient. The light pulses raise the tissue temperature, and the interruptions allow the tissue to have a thermal relaxation response.

A filter 4 filters different portions of the visible spectrum of the light emitted by the light source 2. For example, the visible blue range (400-500 nm) is effective for photopolymerization, and the visible green range (480 –590 nm) is effective for surgical procedures. The filter can include a series of wavelength-specific filters that are actuated by a solenoid (not shown) to move them into the optical path. The filtering also can also be accomplished by either a filter or an optical coating on either end of the fiber optic delivery guide for each individual application. In addition, there may be multiple outlet ports, as well as multiple configurations of application-specific fiber optic guides, handpieces, and cannulas.

A control panel 5 allows an operator to control the apparatus using either a foot switch 9 or a finger control (not shown) in the handpiece 7. Remote control also is an option. The apparatus can operate as a stand-alone unit or it can be integrated into multiple operatories. The apparatus also can be integrated into traditional dental control units or into a high-tech accessory dental unit. In addition, the apparatus can be controlled by a separate foot pedal, or a foot pedal connected to a dental chair or a switch in the handpiece of the dental instrument.

The pulsed light beam generated by the apparatus of this invention is delivered to the tissue 10 through the optical fiber assembly 6, the handpiece 7, and the cannula 8.

Figure 2 shows a detailed view of the control panel 5. Control switches are provided, including a switch 21 to control the power selection, a switch 22 to control the selection of pulsing or continuous operation, and a

switch 23 to control the selection of color. The color selection switch selects the portion of the visible light spectrum that the operator desires to use, such as the wavelength range for blue light (400-500 nm) or for green light (480-590 nm), as discussed above.

The apparatus has multiple outlet ports 26, which allow the apparatus to be used for soft tissue surgery, photopolymerization, bleaching, illumination, caries detection, and shade matching for cosmetic dentistry. This feature allows the operator to perform two or more operations simultaneously.

A reflector (not shown) that is part of the light source 2 has a focal point that either is in the longitudinal axis or is off-axis to the hot spot of the bulb. The hot spot is a section of the bulb (filament or arc) in which the maximum brightness occurs. This is substantially brighter than other sections of the light source. The bulb preferably is positioned so that this hot spot is coincident with the reflector's focal point.

The patient contact tool (i.e., the handpiece 7 and the cannula 8) may be detached from the optical fiber assembly 6 and sterilized in an autoclave, whereas the fiber optic guide may be autoclavable or disposable.

A microprocessor (not shown) controls the apparatus' various operating parameters, based on inputs from the control switches, etc. In addition, the microprocessor can select pre-set operating parameters and automatic default settings for specific applications, as desired by a user.

The microprocessor also may be coupled to one or more remote microprocessors, to allow the tool to be controlled at a site remote from the patient.

Although the invention has been described in detail with reference only to the presently preferred embodiment, those skilled in the art will appreciate that various modifications can be made without departing from the invention. Accordingly, the invention is defined only by the following claims.

What is claimed is

1. A method for performing medical and/or dental procedures on a target biological tissue, comprising:

aiming a high-intensity, polychromatic light beam onto the target biological tissue, to heat the tissue and induce a photo-thermal effect therein; and

pulsing the light beam for a selected duration and duty cycle, such that the tissue undergoes a thermal relaxation response between successive pulses.

2. A method as defined in claim 1, wherein aiming comprises directing the light beam through a light guide having an outlet end disposed adjacent to the target biological tissue.

3. A method as defined in claim 2, wherein pulsing includes periodically interrupting the light beam prior to its being directed through a light guide in directing.

4. A method as defined in claim 1, and further comprising:

generating a light beam having an initial polychromatic spectrum; and

filtering the light beam to remove a portion of its initial polychromatic spectrum prior to aiming.

5. A method as defined in claim 1, wherein the method is effective as a dental procedure on hard dental tissue, including tooth bleaching, curing of dental composite materials, detecting of caries, cutting of enamel, dentin and bone, desensitizing of dentin, etching of enamel, osteoplasty,

ostectomy, shade matching and other cosmetic procedures, trans-illumination, imaging and/or illumination.

6. A method as defined in claim 1, wherein the method delivers sufficient energy to the target biological tissue to raise the tissue to a temperature in the range of 37° to 175° C.

7. A method as defined in claim 5, wherein the polychromatic light beam aimed at the target biological tissue has a power level of at least about 0.1 watt and includes wavelengths in the range of about 400 to 750 nm.

8. A method as defined in claim 7, wherein the light beam aimed at the target biological tissue has a photo-specific energy density in the range of 10 to 5000 watts/cm^2.

9. A method as defined in claim 1, wherein:

the method is effective as a dental procedure on soft biological tissue; and

the light beam aimed at the target biological tissue has a photo-specific energy density sufficient to cause hyperthermia, coagulation, welding, vaporization, carbonization, and/or rapid cutting.

10. Apparatus for use in treating biological tissue, comprising:

a light source for emitting a high-intensity light beam having an initial polychromatic spectrum, wherein the light source directs the light beam to an effective focal position;

a light guide having an inlet end disposed at the effective focal position of the light source and further having a handheld outlet end, of small

cross-section, configured to be disposed in proximity to the biological tissue to be treated.

11. Apparatus as defined in claim 10, and further comprising:

a pulsing device for pulsing the light beam emitted by the light guide for a selected duration and duty cycle, such that the biological tissue being treated undergoes a thermal relaxation response between successive pulses; and

a filter for removing a portion of the initial polychromatic spectrum of the light beam.

12. Apparatus as defined in claim 11, and further comprising an adapter selectively attachable to the outlet end of the light guide, for directing a portion of the light beam emitted by the light guide to the biological tissue to be treated.

13. Apparatus as defined in claim 12, wherein the filter is carried by the adapter.

14. Apparatus as defined in claim 11, wherein the pulsing device is configured to allow an operator to independently control both the duration and the duty cycle of the successive pulses of light emitted by the apparatus.

15. Apparatus as defined in claim 11, wherein the pulsing device is disposed between the light source and the light guide.

16. Apparatus as defined in claim 10, wherein the apparatus is configured to be suitable for use in dental procedures on hard dental tissue, including tooth bleaching, curing of dental composite materials, detecting of

caries, cutting of enamel, dentin and bone, desensitizing of dentin, etching of enamel, osteoplasty, ostectomy, shade matching and other cosmetic procedures, trans-illumination, imaging and/or illumination.

17. Apparatus as defined in claim 16, wherein the light source is selected from the group consisting of halogen lamps, metal halide lamps, and plasma arc lamps.

18. Apparatus as defined in claim 16, wherein the light source is configured to produce a light beam having a power level in the range of 12 to 500 watts.

19. Apparatus as defined in claim 16, wherein the polychromatic light beam directed to the biological tissue to be treated has a power level of at least about 0.1 watt and includes wavelengths in the range of about 400 to 750 nm.

20. Apparatus as defined in claim 19, wherein the polychromatic light beam directed to the biological tissue to be treated has a photo-specific energy density in the range of 10 to 5000 watts/cm^2.

21. Apparatus as defined in claim 10, wherein the light guide comprises an optical fiber assembly.

22. Apparatus as defined in claim 21, wherein:

the optical fiber assembly includes a bundle of tightly packed optical fibers; and

the inlet end of the optical fiber assembly has a diameter in the range of 1 to 2 mm.

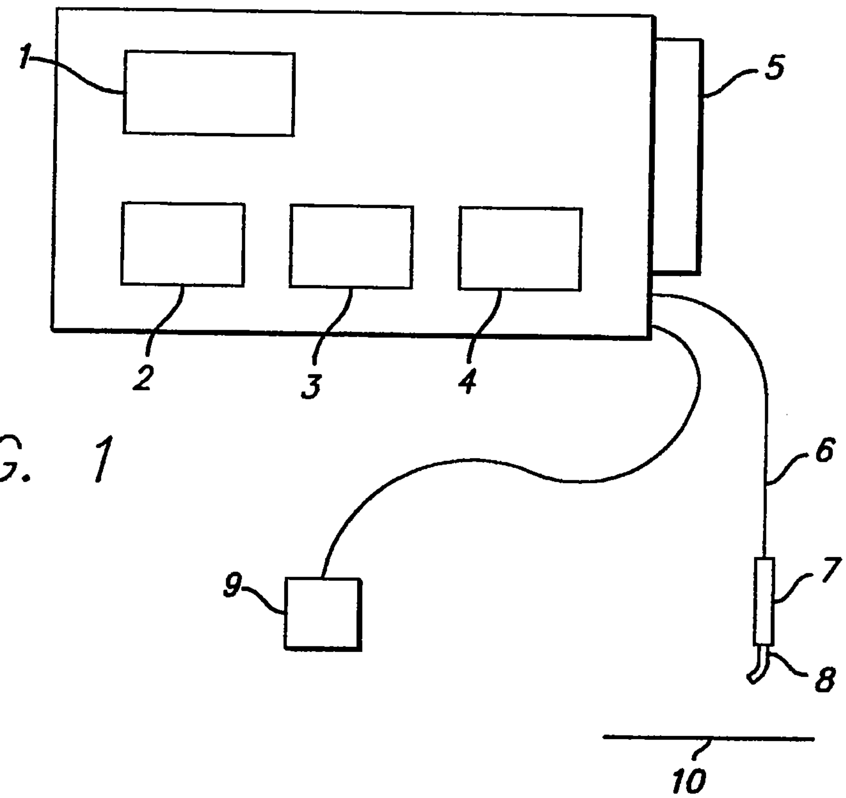

FIG. 1

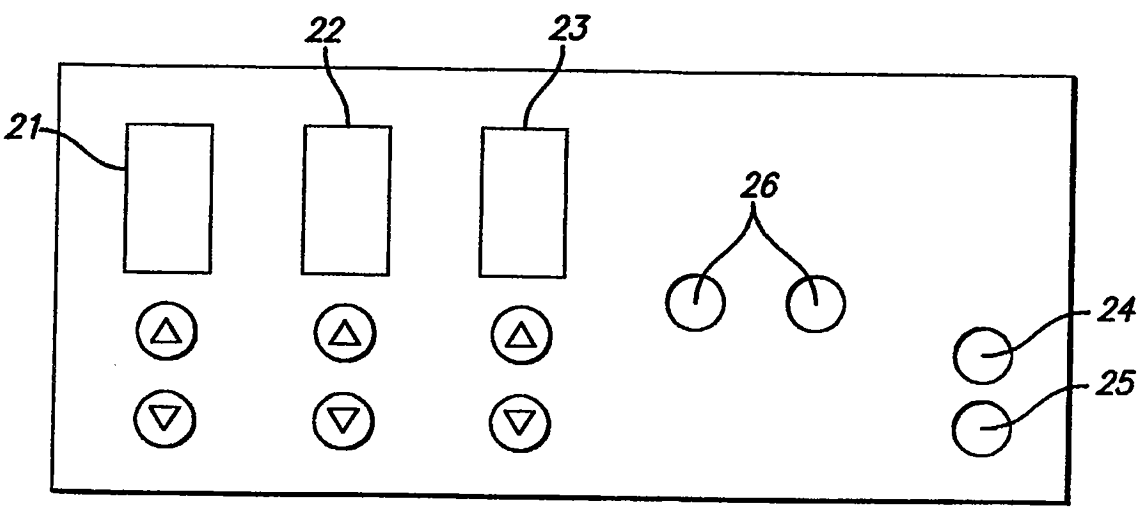

FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/02136

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G02B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 860 172 A (SCHLAGER KENNETH J ET AL) 22 August 1989 (1989-08-22) column 4, line 15 - line 40; figure 1	10-21
X	WO 93 00551 A (GHAFFARI SHAHRIAR) 7 January 1993 (1993-01-07)	10-13, 16-21
A	page 15, line 8 - line 23; claims 1,5; figures 1,5	14,15
X	US 3 327 712 A (KAUFMAN I H ET AL) 27 June 1967 (1967-06-27) column 2, line 65 -column 3, line 6 column 3, line 64 - line 68; figure 1	10,16, 17,19-22
A	US 4 852 549 A (MORI KEI) 1 August 1989 (1989-08-01) column 3, line 16 - line 19; figure 2	16

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 May 2000	19/05/2000

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/02136

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-9
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 00/02136

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